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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,734	09/11/2000	Winfried Edelmann	AHN-001DV1	9039
959	7590	02/09/2006	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 02/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/658,734

Applicant(s)

EDELMANN ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,29-43,45-55 and 57-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13,29-43,45-55,57-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response filed on November 14, 2005 has been received and entered into the case. Claims 24, 44 and 56 are canceled; claims 13, 29 – 43, 45 – 55 and 57 – 41 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 13, 29 – 30, 34 – 43, 45 – 55, 57 – 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for identifying compounds that inhibit meiosis, or stimulate/inhibit chromosome synapsis in a cell, does not reasonably provide enablement for identifying compounds that are useful for preventing fertilization or contraception. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to methods for identifying compounds that prevent fertilization and contraception, however the specification only teaches identifying compounds that affect meiosis and chromosome synapsis. The specification identifies that mice with mutant MSH5 are not fertile and that MSH5 regulates meiosis and is necessary therefore. However the specification

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fails to teach one in the art how these compounds are necessarily useful as contraceptives, or in preventing fertilization. The specification neither provides examples of these compounds nor examples of their effectiveness. Thus the specification fails to enable one in the art how to make, use and practice the claimed invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 13, 29 – 43, 45 – 55 and 57 – 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollingsworth.

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Applicant claims methods for identifying compounds useful as a contraceptive, for inhibiting meiosis, preventing fertilization, inhibiting and stimulating chromosome synapsis. The methods comprise contacting MSH5 protein, MSH5 gene, or a cell expressing MSH5 protein or gene with the candidate compound, determining activity or expression of MSH5 in the presence of the compound, selecting a compound that inhibits MSH5, and identifying the compound useful for a contraceptive, inhibiting meiosis, preventing fertilization and inhibiting chromosome synapsis (or stimulating MSH5 for stimulating chromosome synapsis). The compound may be an antisense MSH5 nucleic acid, inhibitor of MSH5 substrate activity, a small molecule, MSH5 antibody, peptide or peptidomimetic.

Hollingsworth teaches that MSH5 is meiosis specific gene that is active to facilitate meiosis and meiotic chromosome synapsis (abstract) in bacteria, yeast, and humans (p.17290. Hollingsworth additionally teaches that mutant MSH5 (or inhibited activity thereof) results in decreased spore viability (p.1735-6). Thus, Hollingsworth suggests that inhibited or reduced activity of MSH5 inhibits meiosis, chromosome synapsis and decreases fertility.

Although the reference does not teach specific methods for identifying compounds that would inhibit meiosis, stimulate/inhibit chromosomal synapsis, prevent fertilization or act as a contraceptive, Hollingsworth clearly suggests that MSH5 is critical to these activities. Given the teachings of Hollingsworth it would have been obvious to assay for a candidate for meiotic inhibitor, and logically following contraception, by testing putative agents for their ability to inhibit MSHS. Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to assay for such compounds, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant argues that the reference does not teach that MSH5 is meiotic specific and that it facilitates meiosis or chromosomal synapsis; that the relationship is not established in anything other than yeast; that yeast with mutant MSH5 have decrease spore viability; that the yeast are not sexual, thus do not have fertilization.

However, these arguments fail to persuade because the reference teaches the relationship or reduced spore viability, chromosomal synapsis and meiosis as stated above, and as admitted by applicant (regarding the relationship in yeast). While yeast are not sexual, it is noted that the claims are not limited to sexual organisms, mammals or any other organism, but to anything that engages in meiosis and chromosome synapsis. Thus this argument is not commensurate in scope with the claims.

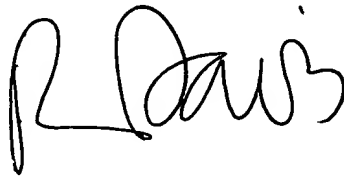
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
February 6, 2006
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A handwritten signature in black ink, appearing to read "R Davis". The signature is stylized with a large, looped "R" and a cursive "Davis".